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12. ABSTRACT

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54. Device for preservation and restoration of adjacent bone walls in body cavities after a surgical procedure

The invention relates to a device (**10**) for the restoration of adjacent bone surfaces (**8**), particularly those involving a fractured orbital fundus in the maxillary sinus (**4**, **5**), with a tetrahedron shaped balloon (**11**), which can be introduced into the body cavity and filled with a fluid from outside. This device is provided with a fluid feed line (**19**) which can be removed from the body cavity. It is joined at one end with the tetrahedron shaped balloon (**11**) and can be attached at the other end to a fluid reservoir (**20**). The invention is characterised in that the tetrahedron balloon (**11**) has one surface (**12**) that is essentially non-elastic in that it cannot be stretched by pulling, but can be bent, and where the other surfaces (**13**, **14**, **15**) of the tetrahedron balloon (**11**) are sufficiently elastic so that during filling with a fluid they bulge out without significant resistance to form a hemisphere.

Description

The invention relates to a device for the maintenance and restoration of adjacent bone surfaces, particularly those involving a fractured orbital fundus in the maxillary sinus, with a tetrahedron shaped balloon, which can be introduced into the body cavity and filled with a fluid from outside. This device is provided with a fluid feed line which can be removed from the body cavity. It is joined at one end with the tetrahedron shaped balloon and can be attached at the other end to a fluid reservoir.

Devices of this type are well known in the form of inflatable balloons that can be introduced into body cavities and filled with fluid from outside the body via a feed line. When the balloon is filled with fluid, the balloon is inflated and exercises pressure on the fractured bone wall of the body cavity which is to be restored in order to maintain the correct anatomical position for the start of the healing process.

Devices like this are used for example in injuries to the bone surfaces of the maxillary sinuses below the orbital cavity and this injury can for example be caused by a blow to the eye area where the eye has been pushed downwards, leading to a fracture of the bone wall.

DE-35 36 516 describes a device of this type whereby the outer contour of the balloon adapts to the inner contour of the body cavity as it fills with fluid, so that the outer contour in the filled state corresponds to the predestined shape of the inner contour, which in the case of reconstruction of the walls of the maxillary sinuses is a tetrahedron.

Using this balloon the fractured bone wall of the orbital cavity will be held up in its anatomically normal position until the end of the healing process. The disadvantage of the device in DE-35 36 516 is that the balloon is not the same shape as the fractured bone wall, as filling the balloon with fluid stretches it to the same extent in all directions, so that as a result of the protrusion of the balloon surface, which lies against the fractured bone wall, the upward pressure is uncontrolled. In addition the arrangement of an additional balloon within the balloon would lead to a complicated and cost-intensive construction of the device.

It is therefore the problem of the invention to create a device for the reconstruction of adjacent bone walls of body cavities, which enables further improvement in holding back the injured bone walls in their anatomically correct position and avoids distortion of the fractured orbital cavity caused by surgical procedures in the maxillary sinuses.

According to the invention the problem is solved by the tetrahedron balloon having a surface that is essentially non-elastic but flexile and the other surfaces of the tetrahedron balloon are elastic enough that each individual surface will expand to form a hemisphere when filled with fluid.

The device according to the invention means that the non-elastic surface of the tetrahedron balloon can be ideally positioned after a surgical procedure against the fractured bone wall of the orbital cavity, without the latter being unnecessarily widened. This will make the adjustment and introduction of the appropriate quantity of fluid significantly easier. The remaining surfaces of the tetrahedron balloon, which apart from the non-elastic surface may each be expanded to form a hemisphere, thus match the inner contours of the rest of the body cavity, so that the surfaces of the balloon opposite the injured bone wall lie flat against the bone wall. When the balloon is inflated in the downward tapering maxillary sinus, it is pushed upwards and thus also supports the large sinuses of the orbital floor. This flat position directly against the fractured bone wall can keep it in a correct and safe anatomical position supported by the non-elastic surface of the balloon. This means the safe and exact positioning of the fractured bone wall is promoted by gradually adapting the balloon to the inner contour of the maxillary sinus.

The following description of the version in the drawing shows further details and advantages of the invention. It shows:

Fig. 1 a diagrammatically simplified representation of a human skull with a device according to the invention arranged in the maxillary sinus, and

Fig. 2 a device according to the invention with fluid reservoir attached.

Fig. 1 is a diagrammatic representation of a human skull **1**. The skull **1** demonstrates two orbital cavities **2** and **3**, where the eyes rest. Below each eye maxillary sinuses **4** and **5** are arranged and these form an essentially tetrahedron shaped inner contour bounded by bone walls. The paranasal sinuses **6** and the oral cavity **7** are also made clear in **Fig. 1**.

To make the type of injury to the maxillary sinuses clear in the diagram, the bone wall **8** of the maxillary sinus **4** is represented in a fractured condition below the orbital cavity **2**. An injury such as this can be sustained for example by a blow to the eye area, in which the eye is pushed downwards, leading to a fracture of the bone wall **8** below the orbital cavity. The normal position of the orbital cavity is illustrated in **Fig. 1** with **8.1** above the fractured bone wall **8**.

To make the treatment of such an injury clear the device according to the invention **9** is arranged in the maxillary sinus **4** and its construction is then explained in detail afterwards in **Fig. 2** where the balloon **11** is represented in operation as a dotted line in the left part of **Fig 1.**

The device according to the invention is labelled **10** in **Fig. 2**. This shows a balloon **11** shaped like a tetrahedron as it is used in the treatment of injuries to the maxillary sinuses, particularly fractures of the orbital floor bone wall **8**. The tetrahedron shaped balloon **11** shows four surfaces **12**, **13**, **14** and **15**, which surround an inner space **16** which can be filled with fluid. In **Fig. 2** the balloon **11** is represented in its filled state, where it has almost taken on its predestined shape. However, this can be filled with a further quantity of fluid, so that surfaces **13**, **14** and **15** can better support the inner edge of the maxillary sinus in order to be able to press the surface **12** against the fractured bone wall **8**. If the bone wall **8** is repositioned during surgery to its original

place, as shown on the right of **Fig. 1**, the balloon **11** is pressed upwards in the maxillary sinus **5** by its inner pressure, which in turn presses it against the repositioned bone wall **8**.

According to the invention one of the tetrahedron surfaces **12** can essentially not be stretched by pulling, so it is non-elastic but can still be bent, while the other surfaces **13**, **14** and **15** of the tetrahedron balloon **11** are elastic so that they can be expanded when filled with fluid and will bulge outwards. The surfaces **12**, **13**, **14** and **15** of the tetrahedron balloon **11** preferably consist of silicone elastomer, and the non-elastic surface **12** is also embedded with fibres to strengthen it, preferably made of polyester, such as polymerised ethylene glycol and terephthalic acid. This fibrous material is shaded in **Fig. 2**.

The non-reinforced silicone elastomer is especially strong and is preferably **0.15** to **0.3** thick, while the silicone elastomer with the fully synthetic fibres is sufficient at **0.2** to **0.4**. [1]

The silicone elastomer embedded with the fully synthetic polyester fibre, has the advantage that it can essentially not be stretched and can be fastened to the rest of the tetrahedron surfaces **13**, **14** and **15** by means of a suture or with silicone adhesive. To avoid confusion of the tetrahedron surfaces **12**, **13**, **14** and **15** by the surgeon, the tetrahedron surface **12** is provided with a coloured mark **17**, although the whole surface can also be coloured. This means it is immediately obvious to the surgeon which is the silicone elastomer surface with the fully synthetic fibres, which should be placed against the fractured bone wall **8**.

If the balloon is not filled with fluid, the material it is made of, which is always tolerated by the body, means it can be folded over for insertion into the maxillary sinuses **4**, **5** using the surgical access route.

According to the invention the attachment part **18** is arranged on the margin of two adjacent surfaces next to the non-elastic surface **12** of the opposite corner of the tetrahedron balloon **11**. This attachment section **18** is formed as a tube and is connected to the inner space **16** of the tetrahedron. By attaching the attachment part **18** in the described area it is with ease possible to arrange the device **9**, **10** according to the invention as required in the right or left maxillary sinus **4**, **5**.

In its preferred form, the attachment part **18** is so arranged at the margin that it separates this in a ratio of 1:2, whereby the shorter section is adjacent to the corner opposite the non-elastic surface **12** of the tetrahedron balloon **11**.

The attachment part **18** is linked to a valve **19**, which is preferably formed as a flexible tube and attached to a fluid reservoir **20** at its head end. The fluid reservoir may be formed as a conventional syringe. The fluid is contained in the fluid reservoir **20**, and will fill the tetrahedron balloon so that it will take on its shape. An incompressible fluid will be particularly advantageous here, such as an aqueous saline solution, as this lends the tetrahedron balloon **11** in its filled state a certain firmness, which will enable optimal positioning of the injured bone wall **8**.

[1] No unit given in patent

Use of the device **9** according to the invention represented in the version in **Fig. 2** is clarified in **Fig. 1** using the maxillary sinus **5**. To introduce the tetrahedron balloon **11** into the maxillary sinus **5** an access **22** is drilled from the paranasal sinus **6** into the maxillary sinus **5**, through which the empty folded up balloon is placed in the maxillary sinus **5**. The attachment piece **18** and the feed line with valve **19** are removed from the nose. After this the tetrahedron balloon is first filled using incompressible fluid, so that during filling the exterior contour of the tetrahedron balloon **11** adapts to the inner contour of the maxillary sinus **5**. During this the surface **12** of the tetrahedron balloon **11** is placed against the fractured bone wall **8**, and the other surfaces **13**, **14** and **15** are supported against the other bone walls, so that the bone wall **8** is held in its anatomically correct position for the fracture to heal (**Fig. 1** right maxillary sinus **5**).

During this time, the line with valve **19** fed through the paranasal sinus **6** to the outside of the head is fastened to a site on the head, such as the side of the nose, which will not excessively hinder the patient.

After healing is complete the tetrahedron balloon **11** is again removed from the maxillary sinus **5** through the nose using the access opening created **22**, and the lead **19** is pulled out of the maxillary sinus **5** through the paranasal sinus, as the broad attachment piece **18** holds open a sufficiently large opening in the bone wall.

Patent claims

1. Device for the preservation and restoration of adjacent bone walls in body cavities after a surgical procedure, particularly those involving a fractured orbital cavity in the maxillary sinus, with a tetrahedron shaped balloon, which can be introduced into the body cavity and filled with fluid from outside and which is provided with a fluid feed line which can be removed from the body cavity and is joined at one end with the tetrahedron shaped balloon and can be attached at the other end to a fluid reservoir, **characterised in that** the tetrahedron balloon (11) has one surface (12) that is essentially non-elastic, but at the same time flexible, and the other surfaces (13, 14, 15) of the tetrahedron balloon (11) are elastic, so that they can each expand into a hemisphere shape when filled with fluid.
2. Device according to claim 1, characterised in that the surfaces (12, 13, 14, 15) of the tetrahedron balloon (11) are preferably made of silicone elastomer, with the non-elastic surface (12) also being reinforced with embedded polyester fibre preferably ethylene glycol and terephthalic acid.
3. Device according to claims 1 and 2, characterised in that the non-elastic surface (12) is marked (17) preferably in colour, to enable correct positioning of the tetrahedron balloon (11) in the maxillary sinus (4, 5).
4. Device according to claims 1-3, characterised in that the non-elastic surface (12) may be laid against the orbital fundus (8).
5. Device according to claims 1-4, characterised in that the attachment part (18) at the margin of two adjacent surfaces is arranged adjacent to the corner of the tetrahedron balloon (11) opposite the non-elastic surface (12).
6. Device according to claim 5, characterised in that the attachment part (18) is preferably arranged at the margin in such a manner that it divides the margin in the ratio 1:2, so that the shorter part is adjacent to the corner of the tetrahedron balloon (11) opposite the surface (12).

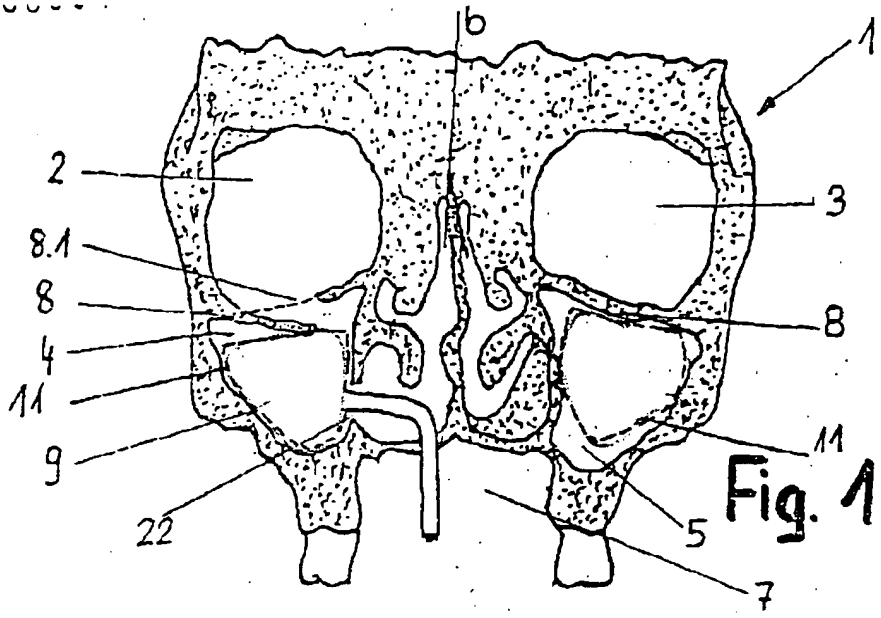

Fig. 1

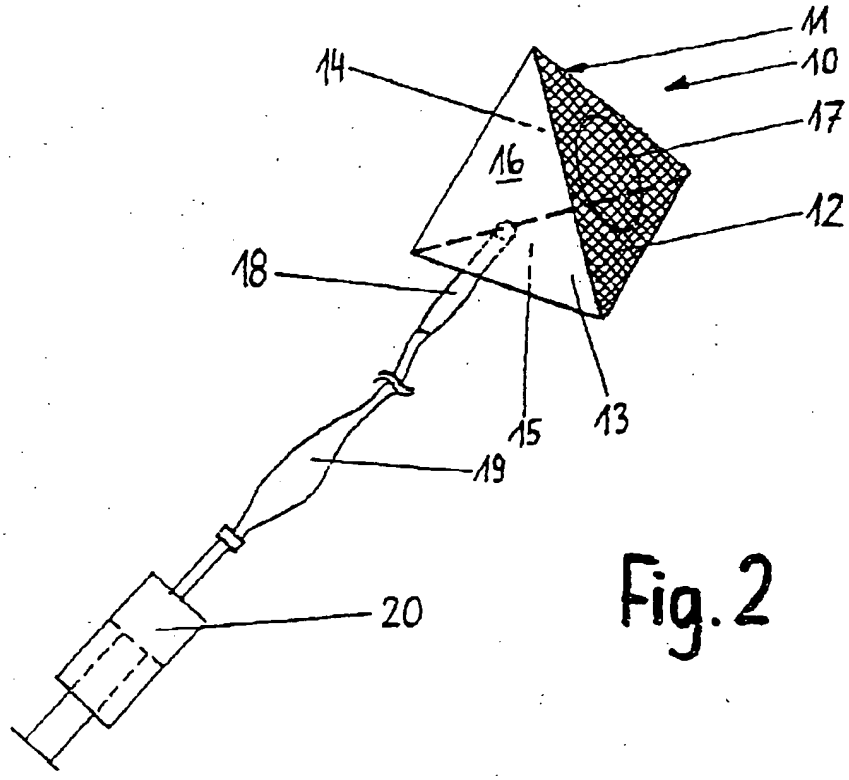

Fig. 2